



Media Alert: 3rd February 2021

Mind Medicine Australia Prepares to Contest TGA's Interim Decision Not to Reschedule Psilocybin and MDMA for Medical Use as Part of Therapy for Key Mental Illnesses

Earlier today the TGA announced its interim decision not to amend the current Poisons Standard in relation to the use of medical grade psilocybin and medical grade MDMA as part of therapy to treat patients suffering from treatment resistant mental illnesses including Depression, PTSD and Substance Abuse. These therapies have been achieving outstanding remission rates in overseas trials, are being used in expanded access schemes in the United States, Canada, Switzerland and Israel and have been shown to be safe and non-addictive when used in medically controlled environments (e.g. hospitals and clinics).

The rescheduling applications were lodged last July and supported by over 80 leading psychiatrists, psychologists, pharmacologists, researchers and other medical practitioners.

In commenting on the interim decisions, the Chairman of Mind Medicine Australia, **Mr Peter Hunt AM**, said that, *"Whilst we are disappointed, we have to remember that these are only interim decisions. The enormous benefit that we now have is that the Secretary of the Department of Health has had to publish his reasons for making these interim decisions. Under the rescheduling process we now have the opportunity to address each of those stated reasons in our final submissions."*

"We believe that the reasons given by the Secretary to justify his interim decisions contain a number of significant errors and omissions and we will be working hard over the next few weeks to draw these to his attention in our final submissions. In the absence of evidence many of the statements amount to nothing more than prejudice."

According to MMA Board member and Executive Director of the Ethics Centre, **Dr Simon Longstaff AO**, *"We should not allow the prejudices of the past to deny relief in the present. If these medicines are safe and effective when applied in a clinical environment, as current research suggests, then Australian governments have an obligation to make them available."*

We also note that the responses given to the TGA about our rescheduling submissions were overwhelmingly supportive and that these included positive responses from world-leading psychiatrists, psychologists, pharmacologists, researchers and other scientists. The numbers are quite startling:

- *In the case of medicinal psilocybin there were 575 responses of which 553 were supportive, 11 partially supportive and only 11 opposed.*
- *In the case of medicinal MDMA, there were 478 responses of which 453 were supportive, 14 partially supportive and 11 opposed.*

"The statement in the Secretary's reasons that few of these responses addressed the factors relevant to rescheduling is simply wrong."



“We also note that a number of the 11 who opposed the rescheduling applications have declined to give the TGA permission to release their submissions publicly. In an open society this “influence behind the scenes” should be completely unacceptable and requires investigation.”

“We remain hopeful that the Secretary will reconsider his position and agree to the rescheduling of these medicines from Schedule 9 (Prohibited Substances) to Schedule 8 (Controlled Medicines). We also note that our rescheduling applications included proposed controls that would mean that these medicines could only ever be used with the patient’s written permission:

- *After the patient had first been screened for suitability by a psychiatrist or specialist addiction physician; and*
- *In medically controlled environments where dosage and the purity of the medicine could be accurately controlled.”*

In Australia the TGA has already given approval for the use of these therapies on a case-by-case basis under Australia’s Special Access Scheme-B. Whilst Victoria has a permit system which applies to these medicines, many other States of Australia still prohibit their use under antiquated recreational drug laws that were never designed for medically controlled therapies. These prohibitions should be urgently reviewed by both the Australian Government and the State Governments in question given the high levels of untreatable mental illness and suicides in our communities.

Executive Director of Mind Medicine Australia, **Tania de Jong AM**, says, *“We live in a country with some of the worst mental health statistics in the World and where an enormous number of people are suffering with treatment resistant conditions. Nothing else is working for them. It is time to give all Australians, who live with multiple failed attempts at recovery, the opportunity to access treatments that will improve and save lives.”*

“As a registered charity we owe it to all of those people who are suffering to overcome prejudice and stigma and to do everything that we can to highlight that these medicines can be used safely in medically controlled environments and therefore should be controlled medicines under the Australian Government’s Poisons Standard.”

Key Dates

Wednesday 3 February 2021 - Interim decisions and reasons published by the TGA. Submission period opens for submissions to be made on the interim decisions from those parties who previously lodged submissions in relation to our rescheduling applications.

Thursday the 4 March 2021 - Final date for second round submissions.

Thursday the 22 April 2021 - Publication of notice of the Secretary’s final decision.



MIND MEDICINE A U S T R A L I A

Mind Medicine Australia is a registered charity (DGR-1 status) working to develop the ecosystem in Australia to enable these therapies to be safely used by skilled practitioners in medically controlled environments to assist patients with treatment resistant depression, treatment resistant PTSD, substance abuse and a number of other major classes of mental illness. The remission rates in overseas trials to date have been very high.

Mind Medicine Australia is wholly focused on the clinical application of psychedelic medicines, and provides a nexus between medical practitioners, academia, government, regulatory bodies, philanthropists and other partners. We support research, and develop therapist training, ethical guidelines, and educational material and events.

Mind Medicine Australia's Board, Management team, Ambassadors, and Advisory Panel members consist of leading practitioners in the applied treatment of mental illness, psychedelic medical research, health strategy, ethics, pharmacology, law and other relevant fields from both Australia and overseas.

Please visit our website for more information about the critical need to introduce Medicine-Assisted Therapies to Australians who are suffering: www.mindmedicineaustralia.org.au

***Further quote:** Tania de Jong AM, Mind Medicine Australia's Executive Director, says, "Unlike conventional treatments, which often require patients to endure years of daily medications and weekly support from a mental health professional, medicine-assisted psychotherapy can be effective after just two to three clinically supervised sessions with these medicines. All the research indicates that the medicines are safe and non-addictive when administered within a medically-controlled environment. There have been no adverse events in over 150 trials globally."*

Please note the following are available for interview:

- **Peter Hunt AM (MMA Chair)**
- **Tania de Jong AM (MMA Executive Director)**
- **Dr Simon Longstaff AO**, Executive Director of The Ethics Centre (**MMA Director**)
- **The Hon. Andrew Robb AO (MMA Director)** - Board Director of MMA and former Trade Minister to Australia who has had treatment resistant depression for 43 years.
- **Chris Barrie AC** - Board Director of MMA and former Head of the Armed Forces who says these treatments are the only hope for Veterans suffering with PTSD.
- **Dr Jamie Rickcord** - who received the first SAS-B approval for a GP to treat a patient with psilocybin-assisted therapy in northern NSW.
- **Michael Raymond** - Veteran in Canberra who has healed through these treatments
- **Shane Hill and his daughter Angelique** - who have healed serious mental illness through these treatments – based in Shepparton VIC.

**For further information, or to arrange an interview, please contact Ilan Hayman ilan@mindmedicineaustralia.org or Tania de Jong tania@mindmedicineaustralia.org
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